05-02-05

1 of 2

Express Mail No. EV577672704US

PETITION FOR CERTIFICATE OF CORRECTION UNDER 37 C.F.R. § 1.322 FOR PATENT AND TRADEMARK OFFICE ERROR Address to: Assistant Commissioner for Patents Washington, D.C. 20231	Attorney Docket Number	LIFE-019
	First Named Inventor	ROBERT SHARTLE
	Application Number	09/879,188
	Filing Date	June 12, 2001
	Patent Number	6,875,613
	Issue Date	April 5, 2004
	Title	*BIOLOGICAL FLUID CONSTITUENT SAMPLING AND MEASUREMENT DEVICES AND METHODS*

Sir:

Applicants petition under 37 C.F.R. § 1.322 for a Certificate of Correction to correct errors in the claims for the above-identified patent due to Patent and Trademark Office error.

Transmitted herewith for filing is a Certificate of Correction for the above-identified patent. Please make the following corrections to Claims 9 and 14.

In Claim 9, column 13, line 25, please replace the word "a" after the word "spaced" and before the word "from" with the word -- apart --.

In Claim 14, column 13, line 43, please replace the word "halving" before the word "at" with the word -- having --.

Enclosed is a copy of the Amendment and Response filed on February 3, 2004, showing the correct form of the Claims. Also enclosed, is a copy of the page of the issued patent showing the incorrect language of the claims that resulted from Patent and Trademark Office error.

It is believed that no fee is due since the error was made by the Patent and Trademark Office. However, the Commissioner is hereby authorized to charge any fees under 37 C.F.R. § 1.20 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-0815.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: 04/28/05 By: _____
Carol M. LaSalle
Registration No. 39,740

Enclosure:
Copy of the Amendment and Response filed on February 3, 2004
Copy of the page containing columns 13 and 14 of the issued patent

BOZICEVIC, FIELD & FRANCIS LLP
1900 University Avenue, Suite 200
East Palo Alto, CA 94303
Telephone: (650) 327-3400
Fax: (650) 327-3231

F:\DOCUMENT\LIFE\019\Certificate of Correction Petition LIFE-019.doc

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 6,875,613
DATED : April 5, 2004
INVENTOR(S) : Robert Shartle et al.

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

In Claim 9, column 13, line 25, please replace the word "a" after the word "spaced" and before the word "from" with the word -- apart --.

In Claim 14, column 13, line 43, please replace the word "halving" before the word "at" with the word -- having --.

MAILING ADDRESS OF SENDER:

BOZICEVIC, FIELD & FRANCIS LLP
1900 University Avenue, Suite 200
East Palo Alto, CA 94303

PATENT NO: 6,875,613

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ber and comprising a hole axially aligned with the channel of the at least one skin-piercing member; and

a constituent transfer medium comprising a hydrophilic material in fluid communication with the channel of the at least one skin-piercing member and with the at least one planar electrode.

2. The device of claim **1** wherein the hydrophilic material comprises a gel matrix.

3. The device of claim **2** wherein the gel matrix comprises a natural gel.

4. The device of claim **3** wherein the natural gel is selected from the group comprising agarose, gelatin, mucopolysaccharide, starch and the like.

5. The device of claim **2** wherein the gel matrix comprises a synthetic gel.

6. The device of claim **5** wherein the synthetic gel comprises a neutral water-soluble polymer.

7. The device of claim **2** wherein the synthetic gel comprises a polymer.

8. The device of claim **7** wherein the polymer is selected from the group consisting of polyvinyl pyrrolidone, polyethylene glycol, polyacrylic acid, polyvinyl alcohol, polyacrylamide, and copolymers thereof.

9. The device of claim **1** wherein the electrochemical cell further comprises a second planar electrodes spaced a from the first planar electrode wherein a reaction chamber is defined there between.

10. The device of claim **9** wherein the distance between the electrodes is from about 50 to 1000 Å.

11. The device of claim **10** wherein the distance between the electrodes is from about 100 to 500 Å.

12. The device of claim **9** further comprising at least one reagent material for chemically reacting with at least one biological fluid constituent, the at least one reagent material located on a surface of at least one electrode facing the reaction chamber, wherein the at least one reagent is selected based on the at least one constituent targeted for measurement.

13. The device of claim **9** wherein the second electrodes is porous and the pores of the second electrode are substantially smaller than the hole in the first electrode.

14. The device of claim **13** further comprising a housing halving at least one vent hole for venting air from within the electrochemical cell.

15. The device of claim **1** wherein the biological fluid interstitial fluid and the analyte is glucose.

16. A kit for sampling biological fluid constituents from the skin of a patient and for measuring the concentration of at least one analyte within the sampled biological fluid constituents, the kit comprising a plurality of devices according to claim **1**.

17. The kit of claim **16** wherein the plurality of devices is disposable.

18. A system for sampling biological fluid constituents from the skin of a patient and measuring at least one target constituent within the sampled biological fluid constituents, the system comprising:

(a) at least one device according to claim **1**; and

(b) a control means in electrical communication with the at least one device, the control means comprising:

(1) means for sending an electrical input signal to the device and for receiving an electrical output signal from the device, and

(2) a software algorithm which automatically calculates and determines the concentration of the target analyte in the accessed biological fluid upon receipt of the electrical output signal.

19. A method for sampling biological fluid constituents within the skin of a patient and for measuring the concentration of one or more target analytes contained therein, the method comprising the steps of:

providing a system according to claim **18**;

operatively applying a first device to the patient's skin wherein the system samples the patient's biological fluid constituents and measures the concentration of the one or more target analytes therein;

removing the first device from the patient's skin;

removing the first device from the, control means;

operatively coupling a second device to control means; and

repeating the above steps until the desired number of samplings and measurements have been performed.

20. The system of claim **18** further comprising a display means in electrical communication with the control means for displaying information in the form of electrical signals received from the control means related to the sampling of the at least one biological fluid constituents and the measuring of the at least one target constituent.

21. The system of claim **20** wherein the device is mounted to the housing by means of a lock-and-release mechanism.

22. A kit for sampling biological fluid constituents from the skin of a patient and for measuring the concentration of at least one analyte within the sampled biological fluid constituents, the kit comprising:

a system according to claim **18**.

23. The kit of claim **22** wherein the control means is reusable.

24. The kit of claim **23** wherein the at least one device comprises two or more reagent materials for testing two or more targeted analytes.

25. The system of claim **18** further comprising a housing wherein the control means is located within the housing and the device is mounted to the housing.

26. The system of claim **25** further comprising user input buttons on the housing for providing user input to the control unit.

27. The system of claim **25** further comprising a display means on the housing for displaying information from the control means.

28. The system of claim **25** wherein the housing has a hand-held configuration.

29. A method for accessing a biological fluid within the skin of a patient the method comprising the steps of:

providing at least one micro-needle comprising an open distal end and a channel therethrough;

inserting the at least one micro-needle into the skin to a selected depth;

absorbing through the open distal end and into the micro-needle channel constituents present within biological fluid present at the open distal end; and

transferring the absorbed constituents through a hole in a conductive material into a measurement chamber, wherein the conductive material is substantially transverse to the at least one micro-needle and the hole is axially aligned with the micro-needle channel.

30. The method according to claim **29** further comprising the steps of:

exerting a capillary force on the sampled biological fluid present in the measurement chamber; and

Atty/Sec: CML/CKH
Atty Docket No. LIFE-019
Application No.: 09/879,188

Date Mailed: February 3, 2004
Filing Date: June 12, 2001

Inventor(s): SHARTLE, ROBERT

Title: "BIOLOGICAL FLUID CONSTITUENT SAMPLING AND MEASUREMENT DEVICES AND METHODS"

Enclosure(s):

- Transmittal (1 pg.)
- Amendment (13 pgs.)
- Terminal Disclaimer for Prior Patent (1 pg.)
- Terminal Disclaimer for Pending Patent Applications (1 pg.)
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* FCE Transmittal + Duplicate (2 pgs.)

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	09/879,188
Filing Date	June 12, 2001
First Named Inventor	SHARTLE, ROBERT
Group Art Unit	1743
Examiner Name	ALEXANDER, LYLE
Attorney Docket Number	LIFE-019

ENCLOSURES (check all that apply)

- [X] Fee Transmittal Form
  - [ ] Fee Attached
- [X] Amendment / Reply
  - [✓] After Final
  - [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Documents
- [ ] Response to Missing Parts/ Incomplete Application
  - [ ] Response to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Assignment Papers *(for an Application)*
- [ ] Drawing(s)
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- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
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- [ ] After Allowance Communication to Group
- [ ] Appeal Communication to Board of Appeals and Interferences
- [ ] Appeal Communication to Group *(Appeal Notice, Brief, Reply Brief)*
- [ ] Proprietary Information
- [ ] Status Letter
- [X] Other Enclosure(s) *(please identify below):*
  1) **Terminal Disclaimer for Prior Patent (1 pg.)**
  2) **Terminal Disclaimer for pending applcations (1 pg.)**
  3) **Return Postcard**

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Signing Attorney/Agent (Reg. No.)	CAROL M. LASALLE, 39,740 BOZICEVIC, FIELD & FRANCIS LLP
Signature	
Date	February 3, 2004

02/03/04
NOA 03/30/04
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PTO/SB/17 (10-03)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 220.00

Complete if Known	
Application Number	09/879,188
Filing Date	June 12, 2001
First Named Inventor	SHARTLE, ROBERT
Examiner Name	ALEXANDER, LYLE
Art Unit	1743
Attorney Docket No.	LIFE-019

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit Account Number: 50-0815

Deposit Account Name: Bozicevic, Field & Francis LLP

The Director is authorized to: (*check all that apply*)

☒ Charge fee(s) indicated below ☒ Credit any overpayments

☒ Charge Any Additional Fee(s) Required under 37 C.F.R. 1.17.

☐ Charge fee(s) indicated below, **except for the filing fee to the above-identified deposit account.**

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) 0.00

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

	Extra Claims		Fee from below		Fee Paid
Total Claims	-20** =		x	=	
Indep. Claims	-3** =		x	=	
Multiple Dependent				=	

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) $ 0.00

**or number previously paid, if greater; For Reissues, see above.

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge – late filing fee or oath	
1052	50	2052	25	Surcharge – late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examination action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive – unavoidable	
1453	1,330	2453	665	Petition to revive – unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1406	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR § 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR § 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	
Other fee (specify) Terminal Disclaimer x's 2					220.00

*Reduced by Basic Filing Fee Paid SUBTOTAL (3) ($) 220.00

SUBMITTED BY				Complete (*if applicable*)	
Name (Print/Type)	Carol M. LaSalle	Registration No. (Attorney/Agent)	39,740	Telephone	(650) 833-7774
Signature				Date	02/03/2004

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TERMINAL DISCLAIMER TO OBVIATE A PROVISIONAL DOUBLE PATENTING REJECTION OVER A PENDING SECOND APPLICATION	Docket Number (Optional) LIFE-019

In re Application of: BIOLOGICAL FLUID CONSTITUENT SAMPLING AND MEASUREMENT DEVICES AND METHODS

Application No.: 09/879,188

Filed: June 12, 2001

For: BIOLOGICAL FLUID CONSTITUENT SAMPLING AND MEASUREMENT DEVICES AND METHODS

The owner*, LIFESCAN, INC., of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application, which would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. 154 to 156 and 173 as shortened by any terminal disclaimer filed prior to the grant of any patent granted on pending second Application Number 09/879,146, filed on June 12, 2001 and 09/878,742, filed on June 12, 2001 of any patent on the pending second application. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent granted on the second application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 to 156 and 173 of any patent granted on the second application, as shortened by any terminal disclaimer filed prior to the patent grant, in the event that any such granted patent: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant.

Check either box 1 or 2 below, if appropriate.

1. ☐ For submissions on behalf of an organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the organization.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2. ☒ The undersigned is an attorney or agent of record.

Signature — Date: 02/03/2004

Carol M. LaSalle
Typed or printed name

☒ Terminal disclaimer fee under 37 CFR 1.20(d) is included.

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*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner). Form PTO/SB/96 may be used for making this statement. See MPEP § 324.

PTO/SB/26 (05-03)
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TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A PRIOR PATENT	Docket Number (Optional) LIFE-019

In re Application of: BIOLOGICAL FLUID CONSTITUENT SAMPLING AND MEASUREMENT DEVICES AND METHODS

Application No.: 09/879,188

Filed: June 12, 2001

For: BIOLOGICAL FLUID CONSTITUENT SAMPLING AND MEASUREMENT DEVICES AND METHODS

The owner*, LIFESCAN, INC., of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application, which would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. 154 to 156 and 173, as presently shortened by any terminal disclaimer, of prior Patent No. 6,501,976. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 to 156 and 173 of the prior patent, as presently shortened by any terminal disclaimer, in the event that it later: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

1. ☐ For submissions on behalf of an organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the organization.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2. ☒ The undersigned is an attorney or agent of record.

Signature

02/03/2004
Date

Carol M. LaSalle
Typed or printed name

☒ Terminal disclaimer fee under 37 CFR 1.20(d) is included.

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AMENDMENT UNDER 37 C.F.R. §1.116	Attorney Docket No.	LIFE-019
	Confirmation No.	4059
	First Named Inventor	SHARTLE, ROBERT
	Application Number	09/879,188
Address to: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Filing Date	June 12, 2001
	Group Art Unit	1743
	Examiner Name	ALEXANDER, LYLE
	Title: "BIOLOGICAL FLUID CONSTITUENT SAMPLING AND MEASUREMENT DEVICES AND METHODS"	

Sir:

This amendment is responsive to the Office Action dated December 30, 2003 for which a three-month period for response was given making this response due on or before March 30, 2004.

The Applicant respectfully requests entry of the following amendments. In view of the amendments and the remarks put forth below, reconsideration and allowance are also respectfully requested.

AMENDMENTS

In the Claims

Please amend claims 1, 9, 13, 40, 42 and 54 as follows:

1. (Currently Amended) A biological fluid constituent sampling and concentration measurement device, said device comprising:

at least one skin-piercing member comprising a proximal end, a distal end, a channel extending from the proximal end to the distal end and a biological fluid access opening at the distal end;

an electrochemical cell for measuring the concentration of analyte within the biological fluid, wherein the cell comprises ~~at least one~~ a first planar electrode positioned substantially transverse to the at least one skin piercing member and comprising ~~at least one pore~~ a hole axially aligned with the channel of the at least one skin-piercing member; and

a constituent transfer medium comprising a hydrophilic material in fluid communication with the channel of the at least one skin-piercing member and with the at least one planar electrode.

2. (Original) The device of claim 1 wherein the hydrophilic material comprises a gel matrix.

3. (Original) The device of claim 2 wherein the gel matrix comprises a natural gel.

4. (Original) The device of claim 3 wherein the natural gel is selected from the group comprising agarose, gelatin, mucopolysaccharide, starch and the like.

5. (Original) The device of claim 2 wherein the gel matrix comprises a synthetic gel.

6. (Original) The device of claim 5 wherein the synthetic gel comprises a neutral water-soluble polymer.

7. (Original) The device of claim 2 wherein the synthetic gel comprises a polymer.

8. (Original) The device of claim 7 wherein the polymer is selected from the group consisting of polyvinyl pyrrolidone, polyethylene glycol, polyacrylic acid, polyvinyl alcohol, polyacrylamide, and copolymers thereof.

9. (Currently Amended) The device of claim 1 wherein the electrochemical cell further comprises ~~two spaced apart~~ a second planar electrodes spaced apart from the first planar electrode wherein ~~defining~~ a reaction chamber is defined there between.

10. (Original) The device of claim 9 wherein the distance between the electrodes is from about 50 to 1000 Å.

11. (Original) The device of claim 10 wherein the distance between the electrodes is from about 100 to 500 Å.

12. (Previously Presented) The device of claim 9 further comprising at least one reagent material for chemically reacting with at least one biological fluid constituent, the at least one reagent material located on a surface of at least one electrode facing the reaction chamber, wherein the at least one reagent is selected based on the at least one constituent targeted for measurement.

13. (Currently Amended) The device of claim 9 wherein ~~both~~ the second electrodes ~~are~~ is porous and the pores of the second electrode are substantially smaller than the hole in the first electrode.

14. (Original) The device of claim 13 further comprising a housing having at least one vent hole for venting air from within the electrochemical cell.

15. (Previously Presented) The device of claim 54 wherein the first electrode comprises pores having diameters in the range from about 25 μm to 200 μm.

16. (Original) The device of claim 15 wherein the diameters are in the range from 50 to 150 μm.

17. (Original) The device of claim 16 wherein the diameters are in the range from about 100 to 150 μm.

18. (Previously Presented) The device of claim 54 wherein the second electrode comprises pores having diameters in the range from about 0.1 to 50 μm.

19. (Original) The device of claim 18 wherein the diameters are in the range from about 0.1 to 10 μm.

20. (Original) The device of claim 1 wherein the biological fluid is interstitial fluid and the analyte is glucose.

21. - 32. (Cancelled)

33. (Original) A system for sampling biological fluid constituents from the skin of a patient and measuring at least one target constituent within the sampled biological fluid constituents, the system comprising:

(a) at least one device according to claim 1; and

(b) a control means in electrical communication with the at least one device, the control means comprising:

(1) means for sending an electrical input signal to the device and for receiving an electrical output signal from the device, and

(2) a software algorithm which automatically calculates and determines the concentration of the target analyte in the accessed biological fluid upon receipt of the electrical output signal.

34. (Original) The system of claim 33 further comprising a display means in electrical communication with the control means for displaying information in the form of electrical signals received from the control means related to the sampling of the at least one biological fluid constituents and the measuring of the at least one target constituent.

35. (Original) The system of claim 33 further comprising a housing wherein the control means is located within the housing and the device is mounted to the housing.

36. (Original) The system of claim 34 wherein the device is mounted to the housing by means of a lock-and-release mechanism.

37. (Original) The system of claim 35 further comprising user input buttons on the housing for providing user input to the control unit.

38. (Original) The system of claim 35 further comprising a display means on the housing for displaying information from the control means.

39. (Original) The system of claim 35 wherein the housing has a hand-held configuration.

40. (Currently Amended) A method for accessing a biological fluid within the skin of a patient, and for sampling constituents therein and determining the concentration of at least one target analyte contained therein, the method comprising the steps of:

providing at least one micro-needle comprising an open distal end and a channel therethrough;

inserting the at least one micro-needle into the skin to a selected depth;

absorbing through the open distal end and into the micro-needle channel constituents present within biological fluid present at the open distal end; and

transferring the absorbed constituents through ~~at least one~~ a hole in a conductive material into a measurement chamber, wherein the conductive material is substantially transverse to the at least one micro-needle and the hole is axially aligned with the micro-needle channel.

41. (Original) The method of claim 40 further comprising the steps of:

causing the sampled constituents to chemically react with a selected reagent within the measurement chamber;

providing a first signal to the measurement chamber; and

receiving a second signal from the measurement chamber, wherein the second electrical signal is representative of the concentration of the target analyte in the accessed biological fluid.

42. (Currently Amended) The method according to claim 40 further comprising the steps of:

exerting a capillary force on the sampled biological fluid present in the measurement chamber; and

transferring the sampled constituents through a second conductive material comprising pores having a size substantially smaller than the hole.

43. (Original) The method according to claim 42 further comprising the step of venting air from the measurement chamber.

44. (Original) The method of 41 further comprising the step of deriving the concentration level of the at least one target analyte in the patient's blood from the second signal.

45. (Original) The method of claim 44 further comprising the step of displaying a numerical value representative of the concentration of the at least one target analyte in the patient's blood.

46. (Original) The method according to claim 45 wherein the step of deriving comprises using a software algorithm.

47. (Original) The method according to claim 41 wherein the accessed biological fluid is interstitial fluid and the at least one target analyte is glucose.

48. (Previously Presented) A method for sampling biological fluid constituents within the skin of a patient and for measuring the concentration of one or more target analytes contained therein, the method comprising the steps of:

providing a system according to claim 33;

operatively applying a first device to the patient's skin wherein the system samples the patient's biological fluid constituents and measures the concentration of the one or more target analytes therein;

removing the first device from the patient's skin;

removing the first device from the control means;

operatively coupling a second to the control ~~unit~~ means; and

repeating the above steps until the desired number of samplings and measurements have been performed.

49. (Previously Presented) A kit for sampling biological fluid constituents from the skin of a patient and for measuring the concentration of at least one analyte within the sampled biological fluid constituents, the kit comprising:

a system according to claim 33.

50. (Previously Presented) The kit of claim 49 wherein the control means is reusable.

51. (Previously Presented) The kit of claim 50 wherein the at least one device comprises two or more reagent materials for testing two or more targeted analytes.

52. (Previously Presented) A kit for sampling biological fluid constituents from the skin of a patient and for measuring the concentration of at least one analyte within the sampled biological fluid constituents, the kit comprising a plurality of devices according to claim 1.

53. (Previously Presented) The kit of claim 52 wherein the plurality of devices is disposable.

54. (Currently Amended) A biological fluid constituent sampling and concentration measurement device, said device comprising:

a first electrode having pores therein;

a second electrode having pores therein and positioned substantially parallel to the first electrode, wherein the second electrode pores are smaller than the first electrode pores;

an electrochemical cell defined between the first and second electrodes;

at least one hollow micro-needle extending substantially transverse to the first electrode wherein at least one pore of the first electrode is axially aligned with the micro-needle, the micro-needle having an open distal end for accessing biological fluid; and

a hydrophilic material contained within at least a portion of the at least one hollow micro-needle and within the electrochemical cell.

REMARKS UNDER 37 CFR § 1.111

Formal Matters

Claims 1-20 and 33-54 were examined and rejected.

By this Amendment, claims 1, 9, 13, 40, 42 and 54 have been amended.

The amendments to the claims were made solely in the interest of expediting prosecution, and are not to be construed as acquiescence to any objection or rejection of any claim.

Support for the claim amendments is found throughout the specification and the drawings and particularly in paragraphs 0038 and 0039. Accordingly, no new matter is added by these amendments.

Claims 1-20 and 33-54 remain pending in the application.

Applicants respectfully request entry of the amendments herein and reconsideration of the application in view of the amendments and remarks made herein.

Double Patenting Rejections

Claims 1-20, 33-39 and 49-53 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 6,501,976. For the reasons presented in the previously submitted Amendment mailed October 7, 2003, Applicant respectfully submits that the claims of the cited patent and of the subject application are patentably distinct as the respective claimed devices are structurally distinct from each other. However, in order to move the prosecution of the pending claims forward, Applicant herein submits the accompanying Terminal Disclaimer with respect to U.S. Patent No. 6,501,976. Accordingly, Applicant's respectfully request withdrawal of this rejection.

Claims 1-20 and 33-53 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent Application Serial No. 09/879,146. While Applicant does not acquiesce to the validity of the rejection, Applicant hereby submits the accompanying Terminal Disclaimer with respect to U.S. Patent Application Serial No. 09/879,146 in order to

move the prosecution of the pending claims forward. Accordingly, Applicant's respectfully request withdrawal of this rejection.

Claims 1-8, 20 and 33-53 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims 1-57 of U.S. Patent Application Serial No. 09/878,742. While Applicant does not acquiesce to the validity of the rejection, Applicant hereby submits the accompanying Terminal Disclaimer with respect to U.S. Patent Application Serial No. 09/878,742 in order to move the prosecution of the pending claims forward. Accordingly, Applicant's respectfully request withdrawal of this rejection.

Claims 9-19 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims 1-39 of U.S. Patent Application Serial No. 09/878,742 in view of Joseph (U.S. Patent No. 5,161,532). For the reasons discussed above, the claims of the subject application are not obvious in view of those of U.S. Patent Application Serial No. 09/878,742 in order to move the prosecution of the pending claims forward. While Applicant does not acquiesce to the validity of the rejection, Applicant hereby submits the accompanying Terminal Disclaimer with respect to U.S. Patent Application Serial No. 09/878,742. Accordingly, Applicant's respectfully request withdrawal of this rejection.

Rejections Under 35 U.S.C. §102

Claims 1-2, 5-8, 20 and 33-54 were rejected under 35 U.S.C. §102(b) as being anticipated by Gough (U.S. Patent No. 4,671,288).

The present invention as claimed in claims 1-2, 5-8 and 20 provides for a planar electrode positioned substantially transverse to at least one skin piercing member and comprising a hole substantially axially aligned with the channel of the at least one skin-piercing member. Claims 33-39 provide for a system comprising a device according to claim 1. Claims 48-53 provide for a method of using the system of claim 33. Claims 40-47 provide for a method of using at least one micro-needle comprising an open distal end and a channel, and transferring absorbed constituents at the open distal end into a measurement chamber comprising a the conductive material substantially transverse to the at least one micro-needle and having a hole substantially axially aligned with the

micro-needle channel. Claim 54 provides for first and second substantially parallel electrodes wherein the second electrode has pores smaller than those of the first electrode, and at least one hollow micro-needle extending substantially transverse to the first electrodes wherein at least one pore of the first electrode is axially aligned with the micro-needle.

While the Examiner correlates the claim limitations of a skin-piercing member/micro-needle, a measurement/electrochemical cell having a planar electrode/conductive material, and a constituent transfer medium with certain elements of Gough's device, the Examiner does not identify an element of the Gough device which provides for or teaches a hole in an electrode/conductive material which is substantially axially aligned with the channel of the skin-piercing member or micro-needle.

It is incumbent upon an Examiner to show that each and every claim limitation of a rejected claim reads on a device or method disclosed in a reference asserted under 35 U.S.C. §102 (see 35 U.S.C. §132). Accordingly, Applicant respectfully asserts that the Examiner has not made a proper rejection under 35 U.S.C. §102.

Notwithstanding the improper rejection, Applicant respectfully asserts that Gough does not disclose, suggest or teach a device and/or method having all of the limitations of the rejected claims. In particular, certain of the rejected claims require a planar electrode/conductive material transverse to a micro-needle/skin-piercing element. Gough's sensors 16 and 18 are wires which are parallel, not traverse, to the needle. Additionally, certain of the rejected claims require the electrode/conductive material to have a hole there through which is axially aligned with a channel of a micro-needle. Gough's sensors do not have holes through them. Others of the rejected claims require that the device have two porous electrodes. As stated by the Examiner in Office Action, Gough does not disclose porous electrodes. Further, certain of the rejected claims require a micro-needle/skin-piercing element having an open distal end. Gough's needle has a closed distal end.

For at least these reasons, claims 1-2, 5-8, 20 and 33-54 are not anticipated nor made obvious in view of Gough. Accordingly, Applicant respectfully requests withdrawal of the rejection and allowance of the claims.

Rejections Under 35 U.S.C. §103

Claims 3 and 4 were rejected under 35 U.S.C. §103(a) as being unpatentable over Gough in view of Nitzan (U.S. Patent No. 5,897,522).

As discussed above with respect to the rejection of claim 1, Gough does not disclose, teach or suggest a device having a planar electrode/conductive material transverse to a micro-needle/skin-piercing element, nor an electrode/conductive material having a hole there through which is axially aligned with a channel of a micro-needle, nor a micro-needle/skin-piercing element having an open distal end. Nitzan fails to make up for the deficiencies of Gough as Nitzan is cited solely for its teaching relating to use of a natural gel matrix. Accordingly, for at least the reasons described above, the combination of Gough and Nitzan fails to render claims 3 and 4 obvious. Applicants respectfully request withdrawal of this rejection and allowance of the claims.

Claims 9-19 are rejected under 35 U.S.C. §103(a) as being unpatentable over Gough in view of Joseph.

As discussed above with respect to the rejection of claim 1, Gough does not disclose, teach or suggest a device having a planar electrode substantially transverse to a micro-needle or having a hole axially aligned with a channel within the micro-needle. Joseph fails to make up for the deficiencies of Gough as Joseph is cited solely for its teaching relating to use of a porous electrode. Accordingly, for at least these reasons, the combination of Gough and Joseph fails to render claims 9-14 obvious.

As discussed above with respect to the rejection of claim 54 and as stated by the Examiner, Gough does not disclose, teach or suggest a device having two porous electrodes. Joseph is relied on solely for its teaching relating to use of a porous electrode and asserts that it would have been obvious to modify Gough in view of Joeseph and use a porous electrode. Applicant respectfully disagrees and asserts that there is no motivation to combine Gough and Joseph. Combining the references as the Examiner suggests provides a device having sensors which are porous. There is absolutely no need for Gough to use porous electrodes let alone porous electrodes which are, in essence, wires. Because the wires have a cross-sectional surface area which are very small relative to the diameter of the needle and run parallel to the needle, there is more than

ample space for biological fluid to freely pass within the needle. Moreover, to place pores or holes within these very thin sensor wires is to substantially reduce their ability to perform their intended function. Again, there is no motivation to combine Gough with the teachings of Joseph because (1) Gough does not have a need for porous electrodes, (2) using porous electrodes in the form of wires as employed in Gough's device is not advantageous to passing fluid through a needle, and (3) using porous electrodes in the form of wires as employed in Gough's device is actually disadvantageous to the proper functioning of the electrodes. Accordingly, for at least the reasons described above, the combination of Gough and Joseph fails to render claims 15-19 obvious.

Applicants respectfully request withdrawal of this rejection and allowance of the claims.

Conclusion

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number LIFE-019.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: 2/3/04

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